

### REMARKS

Support for amended claim 1 can be found at p. 2 line 20 through page 3 line 2; page 3 lines 5-7; page 6 lines 11-14 and 29-31; page 7 lines 3-4 and 6-20; and Figures 5, 8, 9, 11 and 13. Claims 2 and 18 were amended to clarify their language and the amendments are supported at page 5 lines 9-13 and Figure 2. Claim 7 has been amended and the change is supported at page 5 lines 4-7; page 6 line 28 through page 7 line 5; and Figures 8, 9 and 14. Claims 11, 12, 14 and 15 were amended to be consistent with the language of claim 1. The paragraph at line 20 page 2 to line 4 of page 3 was amended to clarify the language. The "Brief Description of the Drawings" was amended as suggested by the Examiner. The paragraph at line 21 page 7 to line 5 of page 8 was amended to clarify the language with regard to Figures 12 and 13. Claim 20 has been canceled. No new matter has been added.

### Election/Restriction Requirement

The Examiner restricted the claims of the present application into four species and required the Applicant to choose one of the four species for further examination. Species 1 includes embodiments represented by Figure 9. Species 2 includes embodiments represented by Figure 11, and species 3 includes embodiments represented by Figures 12 and 13. Finally, species 4 consists of embodiments represented by Figure 14. Timothy Scott made a provisional election of species 3 on February 11, 2003, and Applicant now affirms the election of species 3 of Figures 12 and 13. The Examiner asserts that claims readable on the elected embodiment are claims 1, 2, 4, 7, 8, and 11-15, and has withdrawn claims 3, 5, 6, 9, 10 and 16-33 from consideration.

### Drawings

The Examiner objected to Figure 12 under 37 CFR 1.84(p)(5), because it does not include the reference sign "XII-XII", as mentioned on page 4 line 15. A replacement drawing with the reference sign added has been attached to this reply.

The Examiner objected to Figure 2 as having the reference sign "32," which is not described in the specification. The reference sign has been removed in the attached replacement drawing. The Examiner also objected to Figure 14 as having the reference sign "66," since "66" is not discussed in the text of the application. Applicant has amended Figure 14 to remove the reference sign, and a corrected drawing is attached.

### Specification

The Examiner objected to the specification asserting that the embodiments shown in Figures 12 and 13 were not clearly described in the specification, and specifically points to the description of the figures at page 7 lines 21-24 as being unclear. Applicant has amended the specification as indicated above to clarify the description of the embodiments shown in Figures 12 and 13. The amendment is supported by the figures themselves and at page 6 lines 13-14.

The Examiner further asserted that the base being circumferentially disposed around the valve body as in claim 2 and in claim 4, which depends from claim 2, lacked antecedent basis in the specification and drawings. Applicant has amended claim 2 to clarify the language and provide proper antecedent basis. Support for the amended claim is found in the specification at page 5 lines 9-13 and in Figure 2.

The Examiner pointed out that "apertures or apertures" appeared at lines 24 and 28 of page 2, and the paragraph at page 2 line 20 to page 3 line 4 has been amended to replace the phrase where it occurs to read the "apertures or holes," as suggested by the Examiner.

As proposed by the Examiner, the "Brief Description of the Drawings" (page 3 line 25 to page 4 line 16) was amended to include a brief description of Fig. 14 and at page 4, line 4 "V-V" was corrected to read "VI-VI."

#### Status of Claims

Claims 1-33 are pending. Claims 3, 5, 6, 9, 10 and 16-33 have been withdrawn from consideration at this time. Claims 13-15 have been rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Claims 1, 2, 4, 7, 8, 11 and 12 have been rejected under 35 USC §102(b) as being anticipated by Reger US 5,258,023. Claims 13-15 have been rejected under 35 USC §103(a) as being unpatentable over Reger '023 in view of Lane US 5,147,391. Claims 1, 2, 4, 7, 8, 11 and 12 have been rejected under 35 USC §103(a) as being unpatentable over Campbell et al. WO 00/23006 in view of Reger '023. Applicant respectfully requests reconsideration of the present claims in view of the foregoing amendments and the following remarks.

#### Rejection under 35 USC §112, second paragraph

The Examiner contends claims 13-15 are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner asserts that there is insufficient antecedent basis for the limitation "the suture apertures" recited in claim 13. Applicant has amended claim 13 as suggested by the Examiner replacing said phrase with "the apertures." Based on the amendment made to the claims, Applicant requests that the rejections under 35 USC §112, second paragraph, be withdrawn.

#### Rejection under 35 USC §102(b)

The Examiner contends that claims 1, 2, 4, 7, 8, 11 and 12 are anticipated by Reger '023. Applicant respectfully disagrees with the Examiner's contention. Amended claim 1 recites a prosthetic heart valve having a polymeric valve body and a stent that is at least partially embedded in the polymeric valve body. The stent can be embedded by molding the stent into the polymeric valve body, while simultaneously forming the leaflets (page 6 lines 11-13), and "Care should be taken to insure a satisfactory bond between the polymeric material and the stent" (page 7 lines 10-11).

Reger '023 teaches a prosthetic heart valve having a stent frame and a separately fabricated unicast or extruded valve leaflet apparatus (col. 3 lines 7-8, col. 4 lines 2-3, col. 7 lines 23-26, col. 13 line 65 to col. 14 line 6, and claim 1) that is affixed (e.g., sewed) to the stent frame (col. 4 lines 12-13, col. 13 line 9-13 and claim 1). Reger '023 teaches that the leaflet valve apparatus has means for attaching it to the stent (claim 1 of Reger '023), and does not teach embedding the stent in the valve leaflet apparatus. Reger '023 does not teach a prosthetic heart valve comprising a stent that is at least partially embedded in a polymeric valve body, as in independent claim 1 of the present application.

Claims 2, 4, 7, 8, 11 and 12 depend from claim 1, and since claim 1 can be distinguished over the art of record, Applicant respectfully submits that amended claims 1, 2, 4, 7, 8, 11 and 12 are not anticipated and are allowable over the art of record. Accordingly, Applicant respectfully requests withdrawal of the 35 USC §102(b) rejection.

Rejection under 35 USC §103(a)

Claims 13-15 were rejected under 35 USC §103(a) as being unpatentable over Reger '023 in view of Lane '391. Claims 13-15 depend from independent claim 1, and therefore incorporate the limitations of that claim. Claims 13-15 teach a stent that is at least partially

embedded in a polymeric valve body, wherein the valve body comprises at least one leaflet. As explained above, Reger '023 does not teach a stent embedded in a polymeric valve body.

Lane '391 teaches "an attachment system for sewing bioprosthetic leaflets to the frame and clamping the leaflets between the frame and the annular ring" (col. 3 lines 7-10). The inner frame taught by Lane '391 supports the commissures of a prosthetic valve (col. 2 lines 61-65). Lane '391 teaches cutting leaflets "from a flat sheet of biocompatible material" (e.g., bovine pericardial tissue) (col. 7 lines 31-32). The leaflets are then stitched (col. 8 line 31-36) to the frame. Thus, Lane '391 does not teach a stent that is embedded in a valve body comprising at least one leaflet, as in the claimed invention. Neither Lane '391 nor Reger '023 taken alone or together teach a stent that is at least partially embedded in a valve body, thus claims 13-15 should be allowable over the cited art.

The Examiner rejected claims 1, 2, 4, 7, 8, 11 and 12 under 35 USC §103(a) as being unpatentable over Campbell et al. '006 in view of Reger '023. The prosthetic heart valve of claim 1 comprises a stent having a plurality of apertures providing openings between the inside and outside of the valve that are capable of receiving fasteners (e.g., sutures) for attaching a sewing ring to the valve. As pointed out by the Examiner, Campbell et al. '006 does not teach a stent having a plurality of apertures as in the claimed invention.

Campbell et al. '006 teaches a separate sewing ring that may be coupled to a portion of a stent that is outside the valve body (page 2 lines 9-16). The coupling between the stent and the sewing ring can comprise sutures or cloth (page 2 lines 13-14), and the coupling does not involve apertures in a stent, as in the claimed invention.

Reger '023 teaches a stent that comprises a frame and covering for the frame (claim 1 Reger '023). Reger '023 does not teach a separate sewing cuff that can be coupled to the heart

valve using apertures in the stent, as in the present application. Rather Reger '023 teaches that sewing rings "are contiguous segments of a stent cover 106 which, in large measure covers and protects a supporting frame 110" (col. 7 lines 43-45, col. 3 lines 25-40 and Figure 1). As explained above, Reger '023 also does not teach a stent that is at least partially embedded in a valve body or apertures capable of receiving sewing ring fasteners, as in the claimed invention.

The teachings of Campbell et al. '006 and Reger '023 taken alone or together do not teach a prosthetic heart valve having a stent having apertures capable of receiving sewing ring fasteners to attach a sewing ring, as in the claimed invention.

### CONCLUSION

Applicant respectfully submits that claims 1, 2, 4, 7, 8, and 11-15, as amended, define patentable subject matter. Accordingly, the Applicant respectfully requests allowance of these claims.

Should the Examiner believe that anything further is necessary to place the application in better condition for allowance, the Examiner is respectfully requested to contact Applicant's representative at the telephone number listed below.

Respectfully submitted,

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